

Exhibit C

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

**IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION**

MDL No.: 2327

**THIS DOCUMENT RELATES TO:
LINDA BRYCE, et al.
Civil Action No.: 2:16-cv-06293**

**RULE 26 CASE SPECIFIC EXPERT
REPORT OF KONSTANTIN WALMSLEY, M.D.**

I am Dr. Konstantin Walmsley. Any medical opinions rendered in this report represent my opinions, all held to a reasonable degree of medical certainty, and are based on a reasonable medical probability and scientifically reliable evidence. All opinions are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature.

I. QUALIFICATIONS

I am a licensed physician in the State of New Jersey and a board-certified urologist. I am familiar with the evaluation and treatment of pelvic organ prolapse and stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices. Specifically, I am familiar with Ethicon, Inc.'s ("Ethicon") products, including but not limited to the Prolift and TVT-O products. I have implanted these devices in my patients. I have attended training provided by mesh manufacturers, including Ethicon, regarding these devices. I have reviewed the IFU's for the Ethicon products and reviewed the independent medical literature. Additionally, I have explanted and performed other revision procedures on SUI and POP kits.

In light of my training, knowledge, experience, and qualifications set forth above and in the attached CV, I am familiar with the standards of care applicable in the jurisdiction where the Plaintiff resides as to surgical technique for implantation of the below-referenced Ethicon devices.

Additionally, because of my training, knowledge, experience, and qualifications as set forth above and in the attached CV, I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants. The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, incomplete emptying, and urinary retention), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients' complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

A copy of my CV is attached as Exhibit "A", and a copy of my testimony for the last four years and Fee Schedule is attached as Exhibit "B". The documents I relied upon for this report are contained in Exhibit "C" as well as those documents cited throughout this report.

II. SUMMARY OF CASE SPECIFIC OPINIONS

In formulating my opinions and preparing this report, I reviewed scientific literature, corporate documents from Ethicon, Inc., ("Ethicon"), sample products and depositions

of Ethicon employees and witnesses. The corporate documents, sample products, and depositions were supplied to me by counsel. A list of general materials relied upon and incorporated herein by reference is found within my General Report for these products. Other materials relied upon for this report are listed in Exhibit "C." I have also relied on general causation reports for other Ethicon products. I have reviewed all available medical records in this case. All opinions I have are to a reasonable degree of medical and scientific certainty. I understand that discovery is still ongoing in this case, and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to, corporate documents, depositions, and the expert reports of both Plaintiff and Defense experts. In formulating my opinions herein, I also relied upon my clinical experience in treating stress urinary incontinence.

It is my opinion, to a reasonable degree of medical and scientific certainty, that debilitating injuries Mrs. Bryce suffered, some of which are discussed below, and the majority of her post-implant medical course are a direct result of implanting the Ethicon TVT-Obturator and Prolift mesh devices. As discussed in my general liability reports, the mesh products are not suitable for their intended application as a permanent prosthetic implants for the treatment of pelvic organ prolapse and stress urinary incontinence because of the following characteristics: (a) degradation of the mesh; (b) chronic inflammation and chronic foreign body reaction; (c) mesh that was never intended to be implanted inside the pelvic cavity and is incompatible with the naturally occurring conditions of the vagina including peroxides and bacteria; (d) deformation, rigidity, fraying, roping, cording, and curling of the mesh; (e) loss of pore size with tension; (f) fibrotic bridging leading to scar plate formation and mesh encapsulation; (g) shrinkage/contraction of the encapsulated mesh; and (h) the difficulty and/or impossibility of removing the devices.

As a result, these mesh devices are not suitable for their intended applications as permanent prosthetic implants for pelvic floor repair in women, such as Mrs. Bryce. Ethicon failed to act as reasonable and prudent medical device manufacturer by manufacturing and selling its polypropylene mesh in permanent implants like their TVT-Obturator and Prolift devices. As a result of these and other inadequacies, it is my opinion to a reasonable degree of medical certainty that the implantation of these devices caused Mrs. Bryce to suffer injuries which are permanent in nature. These injuries include: continued and worsening urinary incontinence, urinary retention, urgency, nocturia, polyuria, incomplete bladder emptying, pelvic pain/trauma, adhesions, infections, vaginal tear, chronic constipation, enterocele, cystocele, rectocele, and vaginal pain.

The medical treatment required to treat Mrs. Bryce's injuries caused by the mesh products were a foreseeable result of her complications. In formulating my opinions and preparing this report, I considered the scientific literature, corporate documents from Ethicon, and case-specific materials such as medical records and deposition testimony. I further considered my own clinical experience in treating stress urinary incontinence in my practice. The corporate documents were provided to me by counsel. I have also relied upon the Ethicon TVT-Obturator General Causation report authored by Dr. Bruce Rosenzweig, the Prolift General Causation Report authored by Dr. Abbas Shobeiri, and the Gynecare Prolift General Causation Report authored by Dr. Donald Ostergard in the MDL. All opinions I have offered are held to a reasonable degree of medical and scientific certainty.

III. CASE SUMMARY

Throughout my analysis of Mrs. Bryce's conditions, I have relied upon her medical records and medical history to date. Her medical history is outlined as follows:

At the time of implant, Mrs. Bryce was a 59- year-old gravida 3, para 3 patient. Her three births were vaginal deliveries. Her past medical history was remarkable for hypertension, hypothyroidism, restless leg syndrome, benign breast lump, diverticulitis, colitis, pelvic organ prolapse, grade 2 rectocele, grade 2 cystocele, small enterocele, nocturia, vaginal atrophy, urgency, polyuria, urinary retention and stress urinary incontinence. Her past surgical history was remarkable for benign breast lump removal, breast reduction, tubal ligation, appendectomy, thyroidectomy, cholecystectomy, anterior and posterior colporrhaphy with synthetic mesh, and vault suspension with mesh mid urethral sling. She has never smoked.

On June 13, 2006, Mrs. Bryce underwent laparoscopic cholecystectomy with cholangiogram for symptomatic cholelithiasis under general anesthesia with Dr. John Pyeatt at Boswell Medical Center.

On September 10, 2007, Mrs. Bryce was seen by Dr. Loren L. Faaborg at Banner Boswell Medical Center for an anterior and posterior enterocele repair. Mrs. Bryce's pre- and post-operative diagnosis included cystocele, rectocele, enterocele and stress urinary incontinence. Mrs. Bryce received an anterior posterior enterocele repair, vault suspension with insertion of Prolift mesh, Gynecare TVT-Obturator mid urethral sling, and cystoscopy under general anesthesia performed by Dr. Faaborg. No complications were reported by the surgeon. Mrs. Bryce had complained of urinary incontinence with lifting, sneezing, bending and walking, requiring her to wear a pad constantly. Dr. Faaborg's records indicated she was not sexually active.

On September 2, 2009, Mrs. Bryce was seen at the Emergency Room of Banner Boswell Medical Center complaining of diarrhea, vomiting, abdominal cramping, nausea and left lower quadrant pain which had persisted for 5 days. She was admitted to the hospital with a

diagnosis of acute diverticulitis, diarrhea and possible UTI. During this time, a CT Scan of the Abdomen and Pelvis with IV contrast was performed which showed thickening of the wall of the proximal transverse colon. The CT was interpreted suggesting colitis due to diverticulitis. Mrs. Bryce was advised to obtain an outpatient colonoscopy to rule out other processes. Her discharge diagnosis included the following: abdominal pain, diarrhea, colitis, most likely C. difficile colitis, hypertension, hyperthyroidism, hypokalemia, hypophosphatemia, dehydration and history of B12 deficiency.

On September 1, 2015, Mrs. Bryce saw Dr. Lee Koon of Desert West OB/GYN with complaints of feeling that she did not empty her bladder completely. She complained that her urinary symptoms were worsening and that she needed to bend and wiggle to urinate. Dr. Koon assessed her with chronic urinary retention and suggested that she might need a revision to her sling. He recommended she return to the clinic for a post void residual check and voiding trial. On October 5, 2015, she returned to have the voiding trial during which she received 300 cc of saline and then voided 325 cc. She received a prescription for Macrobid 100 mg.

On April 25, 2017, Mrs. Bryce returned to Dr. Koon with complaints of moderate daily urinary incontinence symptoms. She complained of frequent urination, nocturia, polyuria and urgency, along with vaginal burning. Upon physical examination, Dr. Koon noted a laceration at the posterior forchette. He prescribed Estrogen. Her urine culture contained no bacteria. She returned for reevaluation on May 23, 2017, at which time Dr. Koon noted she had a slight improvement.

IV. CASE SPECIFIC EXPERT OPINIONS

Mrs. Bryce was implanted with Ethicon's Prolift and TVT-Obturator devices on September 10, 2007, and both the TVT-Obturator and the Prolift significantly caused her

injuries. Mrs. Bryce should not have been implanted with the Ethicon TVT-Obturator and the Prolift because the poor design of the devices increased the risk of serious complications and caused her specific complications. These complications include, but are not limited to: continued and worsening urinary incontinence, incomplete bladder emptying, pelvic pain/trauma, adhesions, nocturia, polyuria, urgency, and vaginal burning and pain.

In determining the cause of a specific injury, it is necessary to “rule in” potential causes of the injury and then, by process of elimination, “rule out” the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis or differential etiology and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case. In general, my expert opinions can be summarized as follows:

A. Ethicon’s construction mesh, used in the TVT-Obturator and Prolift devices, is not suitable for its intended application as permanent prosthetic implants for stress urinary incontinence because the pores are too small, it is a heavy weight mesh, it degrades over time, and it can cause chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, biofilm formation and infections; in addition, the mesh has sharp edges, and has been found to rope, curl, and deform. Under tension, the pores have been found to collapse.

B. Ethicon knew that its TVT-Obturator and Prolift mesh devices were not appropriate for use, but it failed to modify/change the mesh to a larger pore size or a lighter weight mesh that would be less likely to degrade, cause excessive foreign body reactions or chronic inflammation, or deform, become rigid, fray, rope, or cord after implantation, and cause the formation of fibrotic bridging that leads to scar plate formation and mesh encapsulation,

which makes these devices difficult if not impossible to remove. According to Ethicon's internal documents, it was unwilling to change the mesh because of its economic interest in maintaining its competitive advantage in the market and, therefore, Ethicon put profits before patient safety.

C. Ethicon's TVT-Obturator and Prolift devices have design flaws because they cannot adequately describe, inform, or explain to physicians how to properly "tension" the device. Further, the devices shrink, contract, rope, and curl making it difficult or impossible to tension in a safe manner for patients.

D. Ethicon's meshes are not suitable for permanent implant because the Material Safety Data Sheet ("MSDS") for the polypropylene resin used to manufacture Ethicon's polypropylene states that its polypropylene is incompatible with strong oxidizers such as peroxides which are readily found in the vagina.

E. Ethicon's mesh devices are also not suitable for permanent implant because the toxicity testing of the polypropylene mesh revealed that it was cytotoxic which can cause cell death and complications.

F. Ethicon's warnings and disclosures of adverse events in their Instructions for Use ("IFU") for these devices have been inadequate based on the adverse reactions and risks associated with them that have been known to Ethicon from the time these devices were first sold and marketed. Ethicon did not disclose information to physicians in their IFU regarding characteristics of their devices that makes them unsuitable for their intended application as a permanent prosthetic implant for pelvic floor repair. This includes - small pore size; heavy weight mesh; the mesh's tendency to degrade over time which causes chronic foreign body reactions, fibrotic bridging, contraction, shrinkage, fraying, loss of particles, roping, curling, or deform; the pores collapsing with tension; the mesh becoming difficult or impossible to remove;

the mesh testing positive for cytotoxicity; and, the MSDS stating that it is incompatible with strong oxidizers, such as peroxides.

G. The design of these devices are flawed because they are not designed for special patient populations, nor does the IFU nor marketing documents inform physicians that certain patients will have poorer outcomes and higher risks.

H. Ethicon failed to reveal material facts about complication and conflicts of interest regarding key studies in key marketing documents.

I. The benefits of these mesh products are outweighed by the severe, debilitating, and life changing complications associated with them and there were safer alternative options available.

J. As a result of the defects in these meshes, Mrs. Bryce suffered and continues to suffer life-long injuries.

Based on my background, education, training, and experience, as well as the medical records and deposition testimony offered in this case, it is my opinion that Dr. Loren L. Faaborg's treatment of Mrs. Bryce met the standard of care. The pre-operative evaluations of the patient met the standard of care. The TVT-Obturator and Prolift meshes were implanted due to complaints of symptomatic grade 2 cystocele and rectocele, with stress urinary incontinence; and surgery was performed within the standard of care with no evidence of surgeon error or deviation from the manufacturer's procedural steps enumerated in the IFU.

After implant of these meshes, Mrs. Bryce developed continued and worsening urinary incontinence, chronic urinary retention, urgency, pelvic pain/trauma, adhesions, infections, nocturia, dysuria, vaginal burning, and vaginal pain. The small pore size, heavy weight mesh, degradation, chronic foreign body response, fibrotic bridging, contracting and shrinking, fraying,

particle loss, biofilm formation and infections, sharp edges, roping, curling and deformation, and the collapsing of pores within the Ethicon TVT-Obturator and Prolift meshes caused these symptoms. Furthermore, her symptoms of continued and worsening urinary incontinence, chronic urinary retention, urgency, pelvic pain/trauma, adhesions, infections, nocturia, dysuria, vaginal burning, and vaginal pain are consistent with known complications such as those described above and is associated with and caused by these mesh products. To a reasonable degree of medical certainty, the meshes implanted and their effects on the surrounding tissues are the causes of Mrs. Bryce's injuries. It is my opinion that both mesh products caused or contributed to the injuries Ms. Bryce suffered, which have been outlined in this report.

Mrs. Bryce's medical history is remarkable for continued and worsening urinary incontinence, chronic urinary retention, urgency, pelvic pain/trauma, adhesions, chronic constipation, infections, cystocele, enterocele, rectocele, nocturia, dysuria, vaginal atrophy, vaginal burning, vaginal tearing and vaginal pain. Mrs. Bryce's conditions included worsening incontinence. The timing of the symptoms, the severity and continual nature of the symptoms, combined with the nature of her conditions provide the relevant information regarding the differential diagnosis.

I did consider her past medical history which included: she was a gravida 3, para 3 patient. All births were vaginal deliveries. Her past medical history was remarkable for hypertension, hypothyroidism, restless leg syndrome, benign breast lump, diverticulitis, colitis, pelvic organ prolapse, grade 2 rectocele, grade 2 cystocele, small enterocele, nocturia, vaginal atrophy, urgency, polyuria, urinary retention and stress urinary incontinence. Her past surgical history was remarkable for benign breast lump removal, breast reduction, tubal ligation,

appendectomy, thyroidectomy, and cholecystectomy. She has never smoked. None of these conditions were factors in her current injuries.

To a reasonable degree of medical certainty, the small pore size, the heavy weight mesh, degradation over time, chronic foreign body reactions, fibrotic bridging, mesh contracture and shrinkage, fraying, particle loss, biofilm formation and infections, sharp edges, roping, curling and deformation, and the pore collapsing with tension of the meshes implanted caused Mrs. Bryce's symptomatology. It is my opinion that she will continue to suffer from long term risks of continued and worsening urinary incontinence, urgency, pelvic pain/trauma, chronic constipation, chronic urinary retention, infection, cystocele, enterocele, rectocele, and vaginal pain. She will likely also continue to experience chronic foreign body reaction and chronic inflammation. As a result, Mrs. Bryce may need additional surgeries to remove remaining Ethicon meshes and treat vaginal scarring, pelvic pain, incontinence, and other injuries associated with the original implantation of the devices. She will have the possibility of future risks and symptoms as long as there is mesh material left in her body. Mrs. Bryce will likely require pelvic floor therapy and physical therapy to alleviate her symptoms which stem from the implant of these devices.

Based on my review of the entire body of literature, my experience, review of Mrs. Bryce's medical records and the deposition testimony provided to me by counsel, it is my opinion, to a reasonable degree of medical certainty, Mrs. Bryce would not have developed the aforementioned symptoms, or the need to undergo additional treatments to the extent that she has, had the Ethicon TVT-Obturator and Prolift meshes never been implanted.

It is my opinion that there were reasonably feasible alternatives available to Ethicon's mesh devices, and for the treatment of Mrs. Bryce. Even other lightweight meshes would have been a safer alternative to the Ethicon meshes implanted in Mrs. Bryce.

Safer alternative designs, rather than the Marlex polypropylene mesh products, existed for this patient. I have experience with many of these safer alternative designs and based on my experience and review of medical literature and other materials, it is my opinion that these alternative designs were safer and feasible for Mrs. Bryce. These safer alternative designs include:

- (1) the use of sutures, including delayed absorbable sutures like PDS, in a native tissue POP repair or Burch colposuspension for SUI;
- (2) autologous fascia sling;
- (3) an allograft sling or POP repair with product such as certain biological graft materials;
and
- (4) a sling or POP repair with less polypropylene such as Ultrapro.

These safer alternative designs were capable of preventing Mrs. Bryce's injuries and damages, as I have described in my report, that were a result of the specific design flaws of the Ethicon TVT-Obturator and Prolift devices using Marlex polypropylene, including degradation, cytotoxicity, stiffness, migration, deformation, fraying, roping, cording, curling, banding, scarring, shrinkage/contraction, scar plate formation, chronic inflammation, chronic foreign body reaction, loss of pore size with tension, dense, heavy, and frayed, rough edges. If any of these safer alternative designs been used for Mrs. Bryce, she would not have suffered the injuries I set

forth in my report, as her injuries were caused by the specific design flaws of the Ethicon TVT-Obturator and Prolift devices discussed above and in my general reports. The likelihood that the Ethicon TVT-Obturator and Prolift designs would cause Mrs. Bryce's injuries and damages and the gravity of those injuries and damages outweighed the burden on Ethicon of adopting such alternative designs and the adverse effects, if any, of such alternative designs on the utility of the Ethicon TVT-Obturator and Prolift products. The inadequate warnings about the Ethicon TVT-Obturator and Prolift devices significantly increased the likelihood of injuries and damages to Mrs. Bryce, and caused or contributed to cause the injuries and damages to Mrs. Bryce. Ethicon failed to use reasonable care to provide adequate warnings to users and handlers of the Ethicon TVT-Obturator and Prolift devices, as discussed herein.

Also, as discussed in my general reports and the report of Dr. Ostergard, Ethicon failed to include and/or describe the significant adverse events and risks in its IFU for these devices. Ethicon did not fully inform physicians about the numerous adverse reactions/risks associated with these devices despite the fact that Ethicon had scientific knowledge of the risks from the time these products were first sold. As a result, physicians, including Mrs. Bryce's implanting physician were unable to fully consent and inform patients of the risk associated with these products. In addition, some risks included by Ethicon in the IFU were mischaracterized to minimize the actual risk. Finally, when given numerous opportunities to update the IFU, and in the face of specific requests to do so from numerous medical professionals - Ethicon did not make the necessary updates.

To a reasonable degree of medical certainty, this prevented physicians and patients from having the ability to make an informed choice regarding the use of the Ethicon TVT-Obturator and Prolift devices. For a surgeon to properly inform the patient of all the known risks included

in any procedure involving an implantable medical device the surgeon relies upon the manufacturer to have scientific knowledge of and convey all characteristics of its products that could impact safety and efficacy. Specifically, surgeons rely on the “Adverse Events/Risks” section of a medical device IFU to gain scientific knowledge regarding adverse events or undesirable effects that the company knows are associated with the product.

For these reasons, and as fully outlined in my general reports, Ethicon failed to advise Mrs. Bryce’s implanting physician of the adverse events and risks associated with the Ethicon TVT-Obturator and Prolift devices. Mrs. Bryce’s implanting physician, Dr. Faaborg, was not fully able to consent her for the procedure because he was not fully aware of what would happen after these meshes were implanted.

Mrs. Bryce’s implanting physician, Dr. Faaborg, did not know about many of these risks prior to implanting her with these devices. Ethicon had knowledge of these risks and therefore, they should have included them in the IFU so that Dr. Faaborg could perform an appropriate risk-benefit analysis. As a result, to a reasonable degree of medical certainty, it is my opinion Mrs. Bryce was damaged by the injuries she suffered that were not disclosed to her implanting physician by Ethicon.

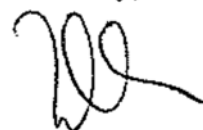
VI. CONCLUSION

To a reasonable degree of medical certainty, it is my opinion that the Ethicon TVT-Obturator and Prolift devices caused Mrs. Bryce’s conditions including continued and worsening urinary incontinence, chronic urinary retention, urgency, pelvic pain/trauma, adhesions, infections, nocturia, dysuria, vaginal burning, and vaginal pain. In addition, it is my opinion to a reasonable degree of medical certainty she will experience continued and ongoing complications and need additional medical treatments in the future related to the permanent complications she

suffered from the inadequacies and implantation of the Ethicon TVT-Obturator and Prolift devices. I reserve the right to amend and/or supplement this report if new discovery or facts necessitate amendment or supplementation.

Dated this August 2nd, 2018.

Sincerely,

A handwritten signature in black ink, appearing to be 'KW' with a long horizontal flourish extending to the right.

Konstantin Walmsley, M.D.

EXHIBIT A

Curriculum Vitae
Konstantin Walmsley, Board Certified in Urology, #14764
November 20, 2015

Address: Urology Group of New Jersey
777 Bloomfield Avenue
Glen Ridge, NJ 07028
(973)725-9096

Date and Place of Birth: April 29, 1970; Philadelphia, PA

Marital Status: Married; one daughter, one son

Education:

1988	Diploma, Collegiate High School for Boys, New York, NY
1992	B.A., Honors in Chemistry, University of Pennsylvania, Philadelphia, PA
1997	M.D., Vanderbilt University Medical College, Nashville, TN

Training and Employment:

Spring 1988	Research Assistant, Dept. of Surgical Metabolism, Memorial Sloan-Kettering Cancer Center, New York, NY Sponsor: Nadarajen Vidylingum, PhD
Fall 1989	Research Assistant, Dept. of Neurosurgery, Graduate Hospital, Philadelphia, PA Sponsor: William J. O'Connor, MD
Summer 1993	Research Fellow, Dept. of Physiology, Diabetes Summer Fellowship, Nashville, TN Sponsor: Alan D. Cherrington, PhD
1993-1994	Anatomy and Problem-Based-Learning Tutor Department of Pathology Vanderbilt University, Nashville, TN
1993-1994	MCAT Instructor Stanley H. Kaplan, Nashville, TN
1995-1996	Howard Hughes Medical Institute—NIH Research Scholar, Laboratory of Tumor Immunology and Biology National Cancer Institute, National Institutes of Health, Bethesda, MD Sponsors: Jeffrey Schlom, PhD
1996-1997	Research Assistant, Dept. of Urology Vanderbilt University Medical College Sponsor: Robert J. Matusik, PhD

6/22/97	Assistant Surgeon
-6/30/98	New York Presbyterian Hospital-Cornell, New York, NY
7/1/98	Clinical Associate in Surgery
-6/30/99	New York Presbyterian Hospital-Cornell, New York, NY
7/1/99	Clinical Associate in Urology
-6/30/03	New York Presbyterian Hospital-Cornell and Memorial Sloan-Kettering Cancer Center, New York, NY
7/1/03- 6/30/04	Clinical Instructor in Female Urology and Voiding Dysfunction New York Presbyterian Hospital-Columbia, New York, NY Director of Urodynamics and Department of Urology Helen Hayes Hospital, West Haverstraw, NY
8/15/04- 10/31/08	Associate Urologist and Clinical Instructor Montclair Urological Group, P.A., Glen Ridge, NJ
11/1/08- Present	Partner, Urology Group of New Jersey, Glen Ridge, NJ

Fellowships and Awards:

1988	National Merit Scholarship Semifinalist
1992	Phi Lambda Upsilon Member (Chemistry Honors Society)
1991	Quarterfinalist, Henley Royal Regatta
1992	Silver Medalist, Lightweight Varsity National Rowing Championships
1992	B.A. awarded with honors for senior thesis
1993	Diabetes Research Summer Fellowship
1993-1997	Microbiology and Immunology Honors Society
1994-1997	Candy Robinson Scholarship Society
1995-1996	Howard Hughes Medical Institute - NIH Research Scholar
1997	John L. Shapiro Award for Excellence in Pathology
2002	Honorable Mention, Research Section, Ferdinand C. Valentine Urology Residents Essay Contest, New York, NY
2003-2004	Fellow in Female Urology and Voiding Dysfunction Preceptor: Steven A. Kaplan, MD
2006-present	Top Doctor, NJ Monthly Magazine
2007-present	Top Urologist, Consumers' Research Council of America
2009-2010	Vice President, Medical Staff, Mountainside Hospital, Montclair, NJ
2011-2012	President, Medical Staff, Mountainside Hospital, Montclair, NJ
2012-2014	Chairman, Board of Trustees, Hackensack University Medical Center-Mountainside, Montclair, NJ
2013-present	Chairman, Department of Surgery, Hackensack University Medical Center-Mountainside, Montclair, NJ
2013-present	Chairman, Credentialing Committee, Hackensack University Medical Center-Mountainside, Montclair, NJ

Activities:

1979-1984	Metropolitan Opera, Boy Soprano
1989-1992	Men's Varsity Lightweight Crew, University of Pennsylvania
1993-1995	Alcohol and Substance Abuse Program Big Brother, Nashville, TN
1997-2003	Cornell Urology Urinary Track Team, 13 marathons completed (personal record 3:04:59)
2012-2016	Completed five ultramarathons

Abstracts and Presentations:

1. "The Conducting and Thermal Properties of Polyaniline Salts" Walmsley K. Honors Program, Chemistry, University of Pennsylvania, Philadelphia, PA, May 3, 1992
2. "The Vanderbilt Transplant Center: Results Between 1998 and 1993" Pinson CW, Walmsley K, Richie RE, Johnson JE, Frist W, Wolff SW. Poster presentation at the *American College of Surgeons*, San Francisco, CA, Oct. 12-14, 1993.
3. "Evidence that the Brain is Directly Sensitive to Physiologic Levels of Plasma Insulin in Vivo" Walmsley K, Dunham BP, Davis SD, Shavers C, Snead WP, Hastings JR, Cherrington AD. Poster Presentation at the *American Diabetes Association Annual Meeting*, New Orleans, LA, June 11-14, 1994.
4. "Vago-Sympathetic Blockade Decreases Basal Hepatic Glucose Production in the Conscious Dog" Walmsley K, Neal DW, Hastings JR, Cherrington AD. Poster presentation at the *American Diabetes Association Annual Meeting*, Atlanta, GA, June 10-13, 1995.
5. "Generation of Human T-Cell Lines Specific for Prostate Specific Antigen Using an Oligo-Epitope Peptide" Walmsley K, Correale P, Nieroda CN, Zaremba S, Tsang, KY, Schlom J. Podium presentation at the *Proceedings of the American Association of Cancer Research*, Washington, D.C., April 22-25, 1996 and *Class of 1995-1996 Scientific Presentations*, Howard Hughes Medical Institute-National Institutes of Health Research Scholars Program, Bethesda, MD, May 22, 1996.
6. "CEA-Specific Cytotoxic T Cell Immunity in Phase I Clinical Trials Using a Recombinant CEA-Vaccinia Vaccine" Tsang KY, Zhu MZ, Nieroda CN, Correale P, Zaremba S, Walmsley K, Schmitz, J, Hamilton, J. Podium presentation at the *Proceedings of the American Association of Cancer Research*, Washington, D.C., April 22-25, 1996.
7. "The Inheritance of Varicoceles" Walmsley K, Goldstein M. Poster presentation at the Annual Meeting of the *American Urologic Association*, Anaheim, CA, June 12-16, 2001. (an AUA CD-ROM top poster presentation).

8. "Varicocele Management in the Pediatric Patient: Results with Microsurgical Varicocoelectomy" Walmsley K, Coleman J, Kelly C, Goldstein M, Poppas DP. Podium presentation at the Annual Meeting of *American Academy of Pediatrics*, San Francisco, CA, October 16-20, 2001.
9. "Effects of Antibody to Transforming Growth Factor Beta in Unilateral Ureteral Obstruction of Mice Lacking the Gene for Inducible Nitric Oxide Synthase" Walmsley K, Seshun SV, Chen J, Ledbetter S, Vaughan ED, Poppas DP, Felsen D. *Ferdinand C. Valentine Urology Residents Essay Meeting*, New York, NY, March 20, 2002. Poster presentation at the Annual Meeting of the *American Urological Association*, Orlando, FL, May 25-30, 2002 (an AUA CD-ROM top poster presentation).
10. "Urodynamic Classification of Overactive Bladder" Flisser AJ, Walmsley K, and Blaivas JG. Podium presentation at the Annual Meeting of the *American Urological Association*, Orlando, FL, May 25-30, 2002.
11. "Sexual Function in Ethnically Diverse Men with Category III Prostatitis/ Chronic Pelvic Pain Syndrome." Okeke Z, Walmsley K, Te AE, and Kaplan SA. Podium presentation at the Annual Meeting of the *American Urological Association*, San Francisco, CA, May 8-13, 2004.
12. "Use of Muscarinic Receptor Antagonists as Monotherapy in Men with Lower Urinary Tract Symptoms who Failed Therapy with Alpha Blockers." Walmsley K, Kaplan SA, and Te AE. Podium presentation at the Annual Meeting of the *American Urological Association*, San Francisco, CA, May 8-13, 2004.
13. "The Diagnosis and Management of BPH." Grand Rounds, Mountainside Hospital, March 8, 2005.
14. "Overactive Bladder and Urinary Incontinence-Treatment Options in the 21st Century." Grand Rounds, Mountainside Hospital, February 6, 2006.
15. "PSA Screening in the 21st Century: The New State of the Art." Grand Rounds, Mountainside Hospital, September 8, 2007.
16. "Updates in the Diagnosis and Treatment of Prostate Enlargement." Grand Rounds, Mountainside Hospital, March 11, 2010.
17. "Hypogonadism: Prevalence, Diagnosis, and Treatment Options." Grand Rounds, Hackensack University Medical Center, April 4, 2013.

Publications:

1. Correale P, Walmsley K, Nieroda, C, Zaremba S, Zhu M, Schlom J, and Tsang KY. In vitro generation of human cytotoxic T lymphocytes specific for peptides derived from prostate-specific antigen *J Natl Cancer Inst* **89(4)**: 293-300.
2. Davis SN, Dunham B, Walmsley K, Shavers C, Neal D, Williams P, Cherrington AD. Brain of the conscious dog is sensitive to physiological changes in circulating insulin *Am J Physiol* **272(4 Pt 1)**: E567-575
3. Correale P, Walmsley K, Zaremba S, Zhu M, Schlom J, Tsang KY. Generation of human cytolytic T lymphocyte lines directed against prostate-specific antigen (PSA) employing a PSA oligopeptide peptide *J Immunol* **161(6)**: 3186-3194.
4. Walmsley K, Te AE. Localized prostate blocks in minimally invasive procedures, *Urologix* 2003, **(3)**: 4-6.
5. Flisser AJ, Walmsley K, Blaivas JG. Urodynamic classification of overactive bladder. *J Urol* 2003 **169(2)**: 529-533.
6. Walmsley K, Staskin DR. Nocturia: When is it not related to overactive bladder? *Curr Urol Rep.* 2003 **4(6)**: 441-445.
7. Walmsley K, Kaplan SA. Transurethral microwave thermotherapy for benign prostate hyperplasia: separating truth from marketing hype. *J Urol.* 2004 Oct;172(4 Pt 1):1249-55.
8. Walmsley K, Gjertsen CK, Kaplan SA. Medical management of BPH- An update. Manuscript pending for *AUA Update Series*.
9. Gjertsen CK, Walmsley K, and Kaplan SA. Benign prostatic hyperplasia: now we can begin to tailor treatment. *Cleve Clin J Med.* 2004 Nov;71(11):857, 860, 863-5.
10. Raman JR, Walmsley K, and Goldstein M. Inheritance of varicoceles. *Urol* 2005 Jun;65(6):1186-9.
11. Kaplan SA, Walmsley K, and Te AE. Tolterodine extended release attenuates lower urinary tract symptoms in men with benign prostatic hyperplasia. *J Urol* 2005 Nov; 174(6): 2273-5.
12. Walmsley K. Genetics in Prostate Cancer. Radiation Oncology Newsletter of Mountainside Hospital 2009 Sept; 1(10): 1-2.

EXHIBIT B

Prior Testimonies

2007 – Mucchiolo vs Steckel et al: (Case in which I was a resident assisting on case with subsequent complications)

2010 – Gonzalez v. Ethicon (case of Ethicon stapler resulting in complications)

2011 – Case in long island involving delay in diagnosis of BPH in patient with urinary retention

2012: Henebury vs. Corea (case of a complication following ureteroscopy)

2013: Schubert vs. Roberts (Prolift complication)

2013 Sorezza vs. Scheuch (case of a complication following PCNL)

3/2014 – Martinez vs. AMS

5/2014 – Humphreys vs Crothall Heath Care (case of possible sexual harassment)

7/2014 – Betancourt vs. BSC

7/2014 – Nunez vs. BSC

11/2014 – Ash vs. Bard; Earls vs. Bard

12/2014 - Curtis vs. BSC; Varnadoe vs. BSC; Curtis vs. BSC; Davis vs BSC

11/2015 – Stewart vs. Meshesha

2/2016 – Del Castillo vs. Caso

3/2016 – Ridgley vs. Ethicon; Fox vs. Ethicon

6/2016: Lindberg vs. Ethicon

6/2016: Manor vs. Ethicon; Martin vs. Ethicon; Pridmore vs. Ethicon; Bailey vs. Ethicon

6/2016: Vanbuskirk vs. Ethicon; Barr vs. Ethicon; Javins vs. Ethicon; Garcia vs. Ethicon

7/2016: Birt vs. Shashoua

8/2016: Birt vs. Ethicon; Baker vs. Ethicon; Ward vs. Ethicon; Phillips vs. Ethicon

10/16: Mattingly vs. Ethicon; Berry vs. Ethicon

11/16: Collins vs. Bard

2/17: Ray vs. Ethicon

COMPENSATION FOR MY REVIEW, STUDY, AND TESTIMONY

My fee for review of medical records, corporate documents and other related materials, testimony, and travel time is an hourly rate of \$500.00 per hour.

EXHIBIT C

Case Specific Reliance List
Linda Bryce
Dr. Konstantin Walmsley, M.D.

Medical Reviewed:

- Desert West OBGYN
- Banner Boswell Medical Center, Loren L Faaburg, M. D.

Litigation Documents Reviewed:

- Short Form File Stamped Complaint
- Plaintiff Profile Form
- Plaintiff Fact Sheet

Materials Reviewed

Depositions of Medical Providers
Depositions of Client and Partner (if applicable)
Expert Reports Related to Case
Medical & Billing Records
Instructions for Use

Boston Scientific Corp.'s TVM products Instructions for Use
Boston Scientific Corp.'s TVM products Patient Brochures

Incorporated Materials

All materials cited in and reviewed for the TVT general causation reports

Medical Literature

AMA 8.08

Boston Scientific Corp.'s TVM products Instructions for Use

C.G. Nilsson et al "Seventeen years' follow-up of the tension free vaginal tape procedure for female stress urinary incontinence." Int. Urogynecol. J. (2013) 24:1265-69

P. Hilton "A clinical and urodynamic study comparing the Stamey bladder neck suspension and suburethral sling procedures in treatment of genuine stress incontinence" British Journal of Obst. & Gynecol (1989), Vol 96, pp. 213-220

H. Enzelsberger et. al "Comparison of Burch and Lyodura Sling Procedures for Repair of Unsuccessful Incontinence Surgery" Obstet & Gynecol, Vol 88, No. 2, August 1996

A.S. Arunkalaivanan et al “Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire based study” *Int. Urogynecol J* (2003), 14: 17-23

K. Guerrero et al “A randomized controlled trial comparing two autologous fascial sling techniques for the treatment of stress urinary incontinence in women: short, medium and long-term follow-up” *Int. Urogynecol J* (2007) 18:1263-1270

U. Klinge, et al. “Shrinking of polypropylene mesh in vivo: an experimental study in dogs”. *Eur J Surg* (1998) 164:965-969.

B. Welk et al, “Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontinence” *JAMA Surgery*, Published Online September 9, 2015.

E.P. Ashok, et al. “Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification”. *European Journal of Obstetrics & Gynecology and Reproductive Biology* (2012), 347- 351.

E. Hurtado, et al “Management of complications arising from transvaginal mesh kit procedures: a tertiary referral center’s experience”. *Int Urogynecol* (2009) J , 11-17.

J.D. Baranowski, et al. “Pain after suburethral sling insertion for urinary stress incontinence”. *Int Urogynecol J* (2013), 195-201.

E. Petri et al., “Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification” *Eur. J. of Obstet. & Gynecol. and Reprod. Bio.* 165 (2010) 347-351

M. Nicklaus Rice, et al. (2013). “Pelvic Mesh Complications in Women Before and After the 2011 FDA Public Health Notification”. *Female Pelvic Medicine & Reconstructive Surgery* (2013), 333-338.

B. Klosterhalfen et al., “Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair” *Biomaterials* (1998) 2235-46

J. Anger et al., “Complications of Sling Surgery Among Female Medical Beneficiaries” *Obstet. & Gynecol.* Vol. 109, No. 3 (March 2007)

H.J. Cholan, et al.. “Dyspareunia with paraurethral banding in the transobturator sling”. *American Journal of Obstetrics & Gynecology* (2010), 481.e1 – e8.

P. Moalli et al, “Tensile Properties of five commonly used mid-urethral sling relative to the TVT” *Int. Urogynecol J* (2008) 19:655-663

- A. Clave et al, "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants" *Int. Urogynecol J* (2010) 21:261-270
- O. Chinthakanan et al., "Mesh Removal Following Sling/Mesh Placement: A Multicenter Study" *Int. Urogynecol. J* (2014) 25 (Suppl 1) S-139-40
- O. Chinthakanan et al, "Indication and Surgical Treatment of MidUrethral Sling Complications: A Multicenter Study" *Int. Urogynecol. J* (2014) 25 (Suppl 1) S-142-43
- E. Petri et al., "Comparison of late complications in retropubic and transobdurator slings in stress urinary incontinence" *Int. Urogynecol. J.* (2012) 23:321-325
- S. Abbott et al., "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study" *American J. of Obstet. & Gynecol* (February 2014) 163.e1-8.
- N. Marcus-Braun, et al." Mesh removal following transvaginal mesh placement: a case series of 104 operations *Int Urogynecol J* (2010) Apr;21(4):423-30
- G. Agnew et al, "Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence" *Int. Urogynecol J.* (2014) 25:235-239
- J. Duckett et al, "Pain after suburethral sling insertion for urinary stress incontinence" *Int. Urogynecol J.* (2013) 24:195-201
- C. Skala et al., "The IUGA/ICS classification of complications of prosthesis and graft insertion" *Int. Urogynecol J* (2011) 22:1429-1435
- K. Svabik et al., "Ultrasound appearances after mesh implantation – evidence of mesh contraction or folding?" *Int. Urogynecol J* (2011) 22:529-533
- Rogowski et al., "Mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair" *Int. Urogynecol J* (2013) 24:2087-2092
- M Tijdink, et al "Surgical management of mesh related-complications after prior pelvic floor reconstructive surgery with mesh". *Int Urogynecol J* (2011), 1395-1404.
- R. Dmochowski et al., "Update of AUA guideline on the surgical management of stress urinary incontinence" *J Urol* (2010) 183:1906
- A. Athanasopoulos et al., "Efficacy and preoperative prognostic factors of autologous rectus sling for treatment of female stress urinary incontinence" *Urology* (2011) 78:1034

Z. Zhan et al., “Long-term follow-up of a multicentre randomized controlled trial comparing tension-free vaginal tape, xenograft and autologous fascial slings for the treatment of stress urinary incontinence in women” *BJU Int* (2015) 115:968

M. Albo et al., “Burch colposuspension versus fascial sling to reduce stress urinary incontinence” *N Engl J Med* (2007) 356: 2143

H Richter et al., “Retropubic versus transobdurator midurethral slings for stress incontinence” *N Engl J Med* (2010) 362: 2066

P Zimmern et al., “Management of recurrent stress urinary incontinence after Burch and sling procedures” *Neurourol Urodyn* (2016) 35: 344